UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/644,387	08/23/2000	Gregory E. Agoston	05213-0541	1513

23594 7590 12/11/2003

JOHN S. PRATT
KILPATRICK STOCKTON LLP
1100 PEACHTREE
SUITE 2800
ATLANTA, GA 30309

EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 12/11/2003

#29

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 29

Application Number: 09/644,387
Filing Date: August 23, 2000
Appellant(s): AGOSTON ET AL.

Robert E. Richards
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 22, 2003.

(1) Real Party in Int rest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-13 and 21-25 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,504,074	D'AMATO et al.	4-1996

5,521,168	CLARK	5-1996
5,643,900	FOTSIS et al.	7-1997
6,200,966	STEWART	3-2001

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-13 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Amato et al. ('074), Clark et al. ('168), Fotsis et al. ('900) or Stewart ('966).

Each of the cited prior art teaches the compound 2-methoxyestradiol and method(s) of using said compound in treatment of a disorder. See each reference as indicated above in #s 3-6.

The instant claims differ from the references by reciting the compound has a purity of greater than 99.5%. However, purification of a compound to be utilized as a pharmaceutical agent would have been obvious to one having ordinary skill in the art at the time of the present invention. Therefore, the ordinary artisan in the art would have the reasonable expectation that the compound taught by the cited prior art references is in pure form.

(11) Response to Argument

Applicant argues (a) the examiner erred in making the final rejection by not considering the lack of appreciation of the art that compounds such as estradiol, estrone, 2-hydroxyestradiol, 4-hydroxyestradiol and 4-methoxyestradiol are undesirable components in a pharmaceutical composition comprising 2-methoxyestradiol and, thus,

the prior art teaches away from the removal of one or more of those components and (b) that Groups I-V are separately patentable because they recite various combinations and concentrations of impurities. Applicant's argument was considered but not persuasive for the following reasons.

Applicant's argument centers on the purity of the prior art compound and the lack of appreciation of the prior art that other steroids that form the impurities are undesirable components. However, the issue is not whether the prior art appreciates the undesirable effects of other steroids but whether it makes obvious 2-methoxyestradiol having a greater than 99.5% purity as recited by the instant claims. As stated in previous Office Actions, it would take only routine experimentation to determine which impurity in a compound is harmful and, thus, removal of said impurity before utilization as a pharmaceutical agent. The motivation would be due to a desire to reduce the adverse effect(s) that might be due to the presence of said impurity. Said determination and purification of pharmaceuticals are routine in the art and well within the level of skill of the ordinary artisan in the pharmaceutical art.

Applicant also argues the compound utilized by Stewart was obtained from Sigma and has provided a Sigma Certificate of Analysis, which discloses 2-methoxyestradiol can be obtained with minimum 98% purity as determined by HPLC. However, applicant argues that the certificate merely states a lower limit of purity and not an obtainable upper limit of purity and that said certificate only supports the fact that up to 2% contamination or impurities is an acceptable level in the commercial 2-methoxyestradiol sold by Sigma. As stated in previous Office Actions, based on the

Sigma Certificate of Analysis it would be obvious to the skilled artisan that 2-methoxyestradiol was obtainable with a purity of greater than 98%. Said conclusion is supported by the present specification (see page 17, lines 5-9 of the present specification). According to the present specification, a sample obtained from Sigma had a purity of **99.2%** as determined by HPLC, which supports the examiner's position that the 98% is a minimum purity obtained by Sigma. The difference between 2-methoxyestradiol having a purity of 99.2%, i.e., purity of the Sigma compound identified by the present specification and a purity of greater than 99.5%, as encompassed by the instant claims, can be considered within the margin of error.

Applicant argues that Groups I-V are separately patentable. However, the examiner's position is that Groups I-V are not separately patentable because of the reasons given above. In addition, the purification and the preparation processes utilized by applicant are known in the art (see pages 8-11 of the present specification). Therefore, the skilled artisan using said processes could readily obtain 2-methoxyestradiol having the various amounts of other steroids as recited by each Group identified by applicant.

In summary, the claimed invention is prima facie obvious because purification of compounds to be utilized as pharmaceuticals is routine in the art and 2-methoxyestradiol was obtainable from Sigma with a purity of greater than the 98% (see page 17, lines 5-9 of the present specification). In addition, the court has held that the mere purity of a compound, in itself, does not render a substance unobvious. Ex parte Gray (BPAI 1989) 10 USPQ2d 1922. The examiner maintains that 2-methyoxyestradiol

in pure form, including greater than 99.5% purity, is obvious based on the prior art and the level of skill of the ordinary artisan in the art.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
December 10, 2003

Conferees
Thurman Page
Sabiha Qazi

KILPATRICK STOCKTON LLP
2400 MONARCH TOWER
3424 PEACHTREE ROAD, NE
ATLANTA, GA 30326

in pure form, including greater than 99.5% purity, is obvious based on the prior art and the level of skill of the ordinary artisan in the art.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

BB
December 10, 2003

Conferees
Thurman Page
Sabiha Qazi

KILPATRICK STOCKTON LLP
2400 MONARCH TOWER
3424 PEACHTREE ROAD, NE
ATLANTA, GA 30326

SABIHA QAZI, PH.D
PRIMARY EXAMINER